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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/517,323 | 12/20/2004 | Masazumi Nishikawa | 263192US0PCT | 3573 |
| 22850 | 7590 | 01/08/2010 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. | | | MERCIER, MELISSA S | |
| 1940 DUKE STREET | | | | |
| ALEXANDRIA, VA 22314 | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 01/08/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

| | | |
|------------------------------|---------------------------------------|---|
| Office Action Summary | Application No. 10/517,323 | Applicant(s) NISHIKAWA ET AL. |
| | Examiner MELISSA S. MERCIER | Art Unit 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 September 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18,19,22,25-36 and 39-41 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 18-19, 22, 25-26, 39-41 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on September 25, 2009 is acknowledged. Claims 18-19, 22, 25-36, and 39-41 remain pending in this application.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-19, 22, 25-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brohuit et al. EP 0321428 in view of Ecomer product information sheet.

Brohuit discloses the use of glycerol ethers in dermatological diseases. The glycerol ethers can be administered orally in the form of capsules and is sold under the TradeName Ecomer (abstract). Ecomer is Shark Liver Oil, see attached product information sheet. The glycerols are present as diesters of fatty acids (column 1, lines 45-48). The capsules contain 0.05g of active substance, thereby meeting the limitation of claim 19. The capsules also contain gelatin and glyercol, which would meet the limitation of claim 31.

Applicant's disclosure on page 8 discloses a method for extracting diacylglyceryl ether, triglycerides, and squalene from shark liver oil. Therefore, it is the examiners position that the use of shark liver oil would inherently possess the ether compound, as well as triglycerides and squalene, in the amounts recited in claim 39, and thus the administration of shark liver oil meets the limitations of the instant claims.

Burns caused by intensive sunrays can be partly prevented by administration (column 1, lines 56-58).

Regarding claim 40-41, the claim limitations are considered to be product by process limitations. Since the prior art discloses the same product used for the same purpose, the process from which it is made does not hold patentable weight. Applicant's attention is directed to MPEP 2113, which discloses, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Burden is shifted to Applicant to provide a patentable distinction between the administration of the shark liver oils of the prior art and that of the instant claims.

Brohuit does not particularly disclose skin cancer induced by UV light, formation of pigmented spots induced by UV light, formation of freckles induced by UV light, formation of wrinkles induced by UV light, formation of verrucae induced by UV light, and formation of erythema induced by UV light as recited in claims 32-36. Martin additionally does not disclose the daily dosage of the composition.

Regarding the dosages recited in claims 19, 25-26, 30, it is the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Regarding the specific conditions of claims 32-36, it would have been obvious to one of ordinary skill in the art to have used the composition of Brohuit for the treatment of UV light induced skin damage since it is disclosed that the ethers beneficially influence diseases depending upon epidermal growth. Since the prior art discloses the composition can be used to treat UV induced skin damage, it would have been obvious to one of ordinary skill in the art to attempt treatment utilizing the composition for the instantly claimed disorders since they all arise from the same origin.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.
Applicant argues:

Claims 40-41 are incorrectly determined to be product by process limitations.

The Examiner disagrees. Claims 40-41 are directed to a product obtained by a particular process. It is suggest that Applicant amend the claims to recite the shark liver oil is degummed in order to overcome the product by process claim rejections. Applicant

Art Unit: 1615

has not provided any evidence that the final product obtained by claims 40-41 is any different from those disclosed by the prior art.

The combined references do not disclose the specific skin damages of claim 18 and the genus does not render obvious the species.

Brohuit discloses the composition is used for the treatment of UV light induced skin damage since it is disclosed that the ethers beneficially influence diseases depending upon epidermal growth. Since the prior art discloses the composition can be used to treat UV induced skin damage, it would have been obvious to one of ordinary skill in the art to attempt treatment utilizing the composition for the instantly claimed disorders since they all arise from the same origin. If the skilled artisan were to therefore administer the compound, it would necessarily also treat the claimed conditions.

Claim 18 also recites the method be preformed on "a subject in need thereof".

The Examiner respectfully submits that any person would be in need thereof reducing skin damage. The patient population is open since the claims do no require that the subject in need thereof is currently suffering from any of the conditions recited in the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615